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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,628	11/23/2001	E. James Squires	6580-234	8447

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DES MOINES, IA 50309-2721

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,628

Applicant(s)

SQUIRES ET AL.

Examiner

David J Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-26 are pending in the application.

Restriction/Election

[2] Applicants' election with traverse of the invention of Group I, claims 1-6, filed October 23, 2003, is acknowledged. The elected invention is drawn to a method for determining the susceptibility of a male pig to developing boar taint.

[3] RESPONSE TO TRAVERSE: Applicants traverse the restriction requirement by arguing that the inventions of Groups I-VII are not independent as, applicants assert, there is a relationship between the groups in that inventions I-VII are directed to boar taint. Applicants further argue Groups VIII-X are related to the method of Group I because the inventions of Groups VIII-X are used to influence or effect the enzymes detected by Group I and the examiner has not provided an alternative use where Groups VIII-X can be used. Applicants also argue Groups VIII-X are not distinct as these compositions all influence skatole metabolism and that only a single search will be required for the claims of Groups VIII-X. Applicants' argument is not found persuasive.

Addressing applicants' argument that Groups I-VII are not independent, applicants assert that all groups are directed to boar taint and thus have a relationship and are dependent. In a previous Office action, the examiner asserted that each of the inventions of Groups I-VII comprise different steps, utilize different products and/or yield

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different results, which is undisputed by applicants. MPEP 806.04 states that two or more inventions are independent if they have “different modes of operation, different functions or different effects.” In this case, each of the methods of inventions I-VII has different modes of operation, different functions or different effects, i.e., the inventions comprise different steps, utilize different products and/or yield different results, and thus, are independent inventions.

Addressing applicants’ argument that Groups VIII-X are related to the method of Group I, contrary to applicants’ assertion, the compositions of Groups VIII-X are unrelated to the method of Group I as these compositions are neither made nor used by the method of Group I, which is again undisputed by applicants. As these compositions are neither made nor used by the method of Group I, there is no requirement that the examiner suggest an alternative use for Groups VIII-X.

Addressing applicants’ argument that Groups VIII-X are not distinct, it is noted that co-examination of the claims of elected Group I with the claims of Groups VIII-X would clearly require a burden on the examiner. An undue burden has been established based on the separate classification of the invention of Group I and the inventions of Groups VIII-X. An undue burden has also been established as the invention of Group I and the inventions of Groups VIII-X require a separate search based on distinct limitations in the claims that would require different text searches using different keywords.

[4] The requirement is still deemed proper and is therefore made FINAL.

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[5] Claims 7-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

[6] Claims 1-6 are being examined on the merits.

Priority

[7] Applicants' claim to domestic priority under 35 U.S.C. 120 to US non-provisional application 09/288,037, filed April 08, 1999 is acknowledged. Applicants' claim to domestic priority under 35 U.S.C. 119(e) to US provisional application 60/081,037, filed April 08, 1998 is acknowledged.

Oath/Declaration

[8] The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: 1) The country of citizenship for inventor Babol listed in the declaration does not correspond to that of the application data sheet filed November 23, 2001 and 2) There is no date accompanying the signatures of the inventors.

Specification/Informalities

[9] The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is

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suggested: -- Method for Determining Susceptibility of a Male Pig to Developing Boar Taint --.

Claim Objections

[10] Claims 1 and 3-6 are objected to because of the recitation of "CYP2E1."

Abbreviations should not be recited in the claims without at least once reciting the entire phrase for which the abbreviation is used. Appropriate correction is required.

[11] Claims 1 and 3-6 are objected to because of the following informalities: the term "sulfotransfease" is misspelled and should be replaced with, for example, "sulfotransferase." Appropriate correction is required.

[12] The preamble of claim 1 states, "[a] method for determining the susceptibility of a male pig," while the body of the claim recites "the pig." In the interest of clarity, it is suggested that applicants amend "the pig" in the body of claim 1 to "the male pig."

[13] Claims 3-6 are objected to because of the following informalities: the term "indicate" appears to be grammatically incorrect and should be replaced with, for example, "indicates." Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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[14] Claim(s) 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claims 1 (claims dependent therefrom) and 2-6 are indefinite in the recitation of "levels." The term is typically interpreted as an amount of a protein. However, the specification discloses that the enzyme activity and not amount is related to a determination of developing boar taint. As such, it is unclear whether the term is meant to be interpreted as an amount of an enzyme or an amount of an enzyme activity. It is suggested that applicants clarify the meaning of the claims. In the interest of advancing prosecution, the examiner has interpreted the term according to its art-recognized definition as being an amount of a protein.

[b] The terms "high levels of CYP2E1," "high levels of a thermostable phenol sulfotransferase," and "low levels of a glucuronyl transferase" in claim 1 (claims 2-6 dependent therefrom) are unclear absent a statement defining to what the levels of the respective enzyme is being compared. The terms are relative terms and the claim should define and clearly state as to what the level of each enzyme is being compared.

[c] Claims 1 (claim 2 dependent therefrom) and 3-6 are indefinite in the recitation of "a thermostable phenol sulfotransfe[r]ase" as it is unclear as to how heat stable a phenol sulfotransferase must be to be included within the scope of the claims.

[d] Claims 2-6 are indefinite in the recitation of "[a] method" and it is suggested that these claims be amended to recite the definite article "[t]he method."

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[e] Claims 3-4 are confusing in the recitation of “the pig has a reduced susceptibility” as it is unclear as to whether “the pig” refers to a female control pig (claim 3) or a male control pig (claim 4) or whether “the pig” refers to the male pig whose susceptibility for developing boar taint is being determined. It is suggested that applicants clarify the claims.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[15] Claim(s) 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn (in relevant part) to a method for determining the susceptibility of a male pig to developing boar taint by measuring the levels of a genus of thermostable phenol sulfotransferases and a genus of glucuronyl transferases. For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or

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chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species of the genus of recited thermostable phenol sulfotransferases, i.e., a sulfotransferase that sulfates 2-naphthol, and only a single representative species of the genus of recited glucuronyl transferases, i.e., a glucuronyl transferase that glucuronidates para-nitrophenol and 2-naphthol. The specification fails to describe any additional representative species of the recited genera of enzymes. While MPEP § 2163 acknowledges that in certain situations “one species adequately supports a genus”, it is also acknowledges that “[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.” In the instant case, the recited genus of thermostable phenol sulfotransferases and glucuronyl transferases encompasses species that are widely variant. As such, the disclosure of the single representative species of thermostable phenol sulfotransferases and glucuronyl transferases is insufficient to be representative of the attributes and features of *all* species encompassed by the recited genus of thermostable phenol sulfotransferases and

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glucuronyl transferases. Given the lack of description of a representative number of species, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[16] Claim(s) 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining the susceptibility of a male pig to developing (synthesizing or forming) boar taint comprising: a) obtaining a liver sample from a male pig and b) immunologically detecting the level of CYP2E1, detecting the rate of glucuronidation of para-nitrophenol or 2-naphthol, or detecting the rate of sulfation of 2-naphthol wherein a high level of CYP2E1, a low rate of glucuronidation of para-nitrophenol or 2-naphthol, or a high rate of sulfation of 2-naphthol as compared to a female control pig or a male control pig or a group of male control pigs indicates that the male pig has a reduced susceptibility to developing boar taint, does not reasonably provide enablement for the methods as encompassed by claims 1-6.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir.

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1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: The claims encompass methods using any sample from the pig and basing the determination of susceptibility of developing boar taint on the levels of any of the recited enzymes, including any thermostable phenol sulfotransferase and any glucuronyl transferase. The broad scope of the claims is not commensurate with the enablement provided by the disclosure. In this case the disclosure is limited to a method for determining the susceptibility of a male pig to developing (synthesizing or forming) boar taint comprising: a) obtaining a liver sample from a male pig and b) immunologically detecting the level of CYP2E1, detecting the rate of glucuronidation of para-nitrophenol or 2-naphthol, or detecting the rate of sulfation of 2-naphthol wherein a high level of CYP2E1, a low rate of glucuronidation of para-nitrophenol or 2-naphthol, or a high rate of sulfation of 2-naphthol as compared to a female control pig or a male control pig or a group of male control pigs indicates that the male pig has a reduced susceptibility to developing boar taint.
- The lack of guidance and working examples: The working examples provided in the specification teach obtaining a sample of liver from the pig for measurement of the

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level of CYP2E1 level, the rate of glucuronidation of para-nitrophenol or 2-naphthol, or the rate of sulfation of 2-naphthol (see Tables 2-3 at pages 52-53 of the specification). Other than the working examples, there is no guidance for determining the susceptibility to developing boar taint using any sample from the pig by measuring levels of any thermostable phenol sulfotransferase or any glucuronyl transferase. The specification provides no guidance as to whether any sample from the pig will have the recited enzymes such that a determination of relatively high/low levels of the enzymes can be made. Further the specification provides no guidance as to whether a determination can be made based on the measurement of enzyme levels of any thermostable phenol sulfotransferase or any glucuronyl transferase. The specification provides evidence that only the rates of sulfotransferase(s) that metabolize 2-naphthol or glucuronyl transferase(s) that metabolize para-nitrophenol or 2-naphthol can be used to predict susceptibility to developing boar taint, not the level of any thermostable phenol sulfotransferase or any glucuronyl transferase. The specification fails to provide guidance that would suggest that increased levels of the enzymes correlate with increased activity. For example, while the enzymes may be present at a higher level, the enzymes may be in an inactive state, and thus are unable to metabolize skatole. It should be noted that there is no indication in the specification as to how one differentiates the level of a thermostable phenol sulfotransferase or a glucuronyl transferase that has the ability to metabolize skatole from the level of a thermostable phenol transferase or glucuronyl transferase that does not.

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- The amount of experimentation required is undue: In view of the overly broad scope of the claims and the lack of guidance and working examples in the specification, one of skill in the art would recognize that the experimentation required to practice the full scope of the claimed methods would not be routine.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the amount of experimentation required, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. As such, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

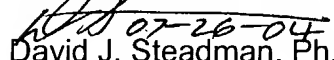
Conclusion

[17] Status of the claims:

- Claims 1-26 are pending.
- Claims 7-26 are withdrawn from consideration.
- Claims 1-6 are rejected.
- No claim is in condition for allowance.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.


David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652